

Authorship in Biomedical Journals

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Thomson Scientific Connexions

February 7, 2007

Agenda

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- ◆ Industry Authors
- ◆ 'Honorary' and 'Guest' Authors
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ICMJE: Definition of an Author (1)

- ICMJE Uniform Requirements (Feb 2006) www.icmje.org
 - Represents >600 international journals
 - Includes major biomedical journals: *Ann Intern Med*, *BMJ*, *JAMA*, *Lancet*, *NEJM*
- ICMJE Authorship criteria:
 - (1) Substantial contributions to conception and design, or acquisition of data, or analysis and interpretation of data
 - (2) Drafting the article or revising it critically for important intellectual content, and
 - (3) Final approval of the version to be published
 - Authors should meet conditions 1, 2, and 3
- Acquisition of funding, collection of data, general supervision of the research group, alone, does not justify authorship

ICMJE: Definition of an Author (2)

Large Multi-Center Groups:

- Group should identify individuals who will accept direct responsibility for the manuscript
- The individuals should meet the criteria for authorship
- All individual authors as well as the group name should be identified
- List other members of the group in Acknowledgements

All those designated as authors should qualify for authorship, and all those who qualify should be listed as authors

Each author should have participated sufficiently in the work to take public responsibility for appropriate portions of the content

ICMJE: Other Contributors

- Those who do not meet authorship criteria should be listed in Acknowledgments, eg,
 - Provided technical help or writing assistance
- Journal Editors should ask authors to disclose writing assistance and who paid for it
- List contributors under a heading such as “Clinical Investigators” and describe their function or contribution “critically reviewed the study proposal,” or “collected data”
- All persons listed must give **written permission to be acknowledged**



Contributorship Model

- ◆ Complementary to ICMJE criteria
- ◆ Now adopted by several journals, eg, *JAMA*, *BMJ*
- ◆ Authors describe exactly what they did, eg,
 - Designing the study
 - Acquiring funding
 - Recruiting patients
 - Coordinating, collecting, and analyzing data
 - Writing/revising the manuscript, etc.
- ◆ Authors also expected to specify their functional role, eg, principal investigator, coinvestigator, statistician
- ◆ This additional layer of disclosure to promote greater transparency of roles/responsibilities

Industry Authors

- According to ICMJE, all individuals should be listed as authors if they meet the 3 criteria
- Some journals recommend a statistician be an author to take responsibility for the statistical analyses
- Some journals may restrict or reject papers by industry authors or sponsored by industry on their company's products or if portraying the company's products favorably
- Some journal policies relating to industry authors are not explicitly stated
- Scicon experience:
 - No obvious issues with industry personnel being listed as authors
 - One recent instance of manuscript rejection because ONLY industry authors, despite checking with journal beforehand

'Honorary' and 'Guest' Authors

- ◆ Authors who do not meet the ICMJE or journal's criteria for authorship
- ◆ Guest author: to improve chance of acceptance
- ◆ Honorary author: tenuous link, eg, head of department
- ◆ Scicon experience, more common in
 - Academia
 - Less experienced authors/sponsors
- ◆ Recommend review of target journal policy/forms and ICMJE criteria

Authorship Forms

- ◆ The more detailed the authorship information or form required by journal:
 - Greater number of contributions reported by authors
 - Greater compliance with ICMJE/journal authorship guidelines
- ◆ **JAMA** has a good example of a detailed authorship checklist
- ◆ Some journals require specific wording/statements re: author contributions and disclosures of conflicts of interest

Authorship Example: JAMA

- ◆ Structured checklist re: contributions for all named authors
- ◆ Each author's specific contributions listed in Acknowledgments
- ◆ For original articles, at least 1 named author (usually PI) who is **independent of any commercial funder** to indicate that she/he “had full access to all the data in the study and takes responsibility for the integrity of the data and the accuracy of the data analysis”; this *exact* statement to be in Acknowledgments

Authorship Example: *BMJ* (1)

● Believes ICMJE definition has serious flaws

- Does not make clear who contributed what to published study, nor who is responsible for overall content
- Excludes those whose sole but often large contribution has been to collect data
- Does not identify an overall guarantor of study and paper

● Identifies contributors in 2 ways

- Authors' names at beginning of paper
- Contributors (some of whom may not be authors) at end of paper, with details of who did what in planning, conducting, and reporting

Authorship Example: *BMJ* (2)

- One or more guarantors required
 - Accept full responsibility for the work and/or conduct of study
 - Had full access to the data
 - Controlled decision to publish
- For articles that do not report original research, eg, reviews articles, request
 - Who had the idea for the article
 - Who performed the literature search
 - Who wrote the article
 - Who is the guarantor

Order of Authors

- ◆ Determine **before** manuscript developed with input from principal investigator (PI), other investigators, industry sponsor, 'publication committee'
- ◆ **Clinical paper:**
 - PI first
 - Co-authors often based on enrollment numbers
 - May also include 'significant contributors' (discuss with PI)
 - Representatives from different countries if a multinational trial
 - May be based on seniority or be alphabetical
 - If industry authors also, may list after external authors
 - Some journals limit number of authors
- ◆ **Review article:**
 - Determine at concept stage, based on likely contributions
 - May be based on seniority or be alphabetical

Acknowledging Medical Writers

- ◆ Scicon has written policy to acknowledge MW contributions (agency and industry), including names and affiliations
- ◆ Many journals require disclosure of **all** contributions, including MW services
- ◆ Disclosure of MW services in high-tier journals:
 - In 6% of research papers, 10% of industry-sponsored studies
 - What % of papers actually involve MW services? 50%?
- ◆ Likely that % of papers disclosing MW services will increase
- ◆ Industry policies re: disclosure of MW services and other contributions
- ◆ Some authors and (more often) industry still resistant
- ◆ Some (few) journals still reject papers where MW services involved (more often EUR)

Conflict of Interest (COI) & Financial Disclosure (1)

- ICMJE states:
 - COI exists when an author (or author's institution), reviewer, or editor has financial or personal relationships that inappropriately influence (bias) his/her actions
- Most journals require authors to disclose actual or potential COI relating to the topic of their paper
- Monetary amounts to be disclosed may vary by journal
- Time period over which financial relationships were in place vary by journal
- Placement in paper and specific wording journal dependent, eg, Acknowledgments, Methods, submission cover letter

Conflict of Interest (COI) & Financial Disclosure (2)

- COI include, but not limited to:
 - Employment or affiliation
 - Consultancy agreements, eg, Ad Boards, Speakers' Bureaux
 - Travel grants
 - Research support or other funding
 - Stock ownership/options
 - Honoraria
 - Paid expert testimony
 - Patents
- Other disclosures include:
 - Study sponsor and role
 - MW services and funding source
- Many journals do not provide specific guidelines; if in doubt, **disclose**

COI Example: *Lancet*

- Avoids commissioning (or considering unsolicited mss) when, within the past 3 years, and with a relevant company or competitor, any of the authors:
 - Has stocks, equity, a contract of employment, or a named position on a company board
 - Has been asked by (or will be asked by) any organization other than *Lancet* to write, be named on, or to submit the paper

Institution Policies

- ◆ Stanford University School of Medicine 'Stanford Industry Interactions Policy' went into effect Oct 1, 2006
- ◆ Section V A states:
 - "Individuals are prohibited from publishing articles under their own names that are written in whole or material part by industry employees"
- ◆ Assume this applies to MW services funded by industry
- ◆ Other institutions may have policies that relate to authorship, industry involvement with publications, conflicts of interest
- ◆ Harvard Medical School policy (1996) "agreements...to permit sponsors to modify materials submitted for publication...are unacceptable"
- ◆ Scicon approach: responsibility lies with the authors/investigators to know their own institution's policy

Resources and Further Reading

- ◆ COPE www.publicationethics.org.uk
- ◆ CSE www.councilscienceeditors.org
- ◆ ICMJE www.icmje.org
- ◆ WAME www.wame.org
- ◆ Bates T, et al. Authorship criteria and disclosure of contributions. JAMA 2004, 292:86-88
- ◆ Godlee F. Reputations for sale. BMJ 334 (Jan 27), 2007
- ◆ Gøtzsche P, et al. Ghost authorship in industry-initiated randomised trials. PLoS Medicine 2007, 4(Issue 1, e19):1-6
- ◆ Graf C, et al. Best Practice Guidelines on Publication Ethics. Int J Clin Pract 2007, 61 (suppl 152):1-26
- ◆ International Congress on Peer Review and Biomedical Publication, Sept 16-18, 2005, Chicago. Abstracts and full papers available via www.ama-assn.org/public/peer/program.html
- ◆ Stanford Industry Interactions Policy http://med.stanford.edu/coi/siip/documents/siip_policy_aug06.pdf

Questions

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